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--26. The method according to claim 22, wherein said transgene encodes for collagen or gastric lipase.--

R E M A R K S

It is believed that the present application has been amended in a manner which places it in condition for allowance at the time of the next Official Action.

In the outstanding Official Action, claims 13-16 and 18 were rejected under 35 USC §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

Applicants respectfully submit that the Official Action fails to meet the burden of showing that the claimed invention is not enabled by the present disclosure. As the Examiner is aware, any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed. *In re Bowen*, 181 USPQ 48 (CCPA 1971), decided concurrently herewith; *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *In re Marzocchi*, 58 CCPA 1069, 449 F.2d 220, 169 USPQ 367 (CCPA 1971). In imposing the enablement rejection,

applicants respectfully submit that the Official Action fails to provide any evidence or reasoning substantiating the assertion that the claimed invention is not enabled.

While the Official Action alleges that the specification does not provide guidance for transforming a male sterile plant with a transgene, or for integrating a transgene genetically linked to an artificial male sterility (AMS) gene into a male sterile plant, it is believed that the Official Action fails to provide any evidence to support this contention.

New claim 19 is drawn to a method for preventing transgene dissemination wherein said transgene is introduced in a plant that carries cytoplasmic male sterility.

Applicants respectfully submit that the production of a plant carrying a cytoplasmic male sterility gene can be readily achieved by one skilled in the art. For example, reference can be made to the document Worrall et al. cited in this examination procedure. Worrall et al. disclose that cytoplasmic male sterility has been studied and even used early in the 1970's (see page 759, left column, second paragraph).

Moreover, classical methods for introducing a transgene in a plant are cited in the specification. For example, the Examiner's attention is respectfully directed to page 10, line 20, to page 11, line 27; Example 3; and Example 4.

Thus, applicants believe that the present specification, in view of the general knowledge in the field of

plant transformation, provides sufficient guidance to enable one skilled in the art to transform a plant with a transgene and carry out the claimed method.

The Examiner's attention is also respectfully directed to new claim 22. New claim 22 is drawn to a method for preventing transgene dissemination wherein a plant is transformed with a transgene of interest genetically linked with an artificial male sterility gene.

Examples 1 and 2 of the present application describe the construction of vectors carrying either PR glucanase, barnase, or dog gastric lipase. PR glucanase and barnase are two examples of genes conferring artificial male sterility. Dog gastric lipase constitutes an example of a transgene of interest.

Thus, transforming a plant with a construct carrying a transgene of interest, genetically linked with an artificial male sterility gene, may be carried out by an appropriate transformation method known in the art. Therefore, applicants believe that one skilled in the art, at the time the invention was made, knew how to produce a transgenic plant.

Thus, applicants respectfully submit that the outstanding Official Action fails to provide any evidence that the claimed invention is not enabled by the present disclosure. Moreover, applicants believe that the present specification clearly teaches one skilled in the art how to make and use the claimed invention. to the contrary. Applicants believe that the

Official Action fails to meet its burden in rendering the claimed invention obvious.

Claims 15-16 and 18 were rejected under 35 USC §112, first paragraph, for allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

The Official Action alleges that the term "plant cultivated for seed or fruit production [reduction]" would not be supported by the specification.

On the contrary, applicants are of the opinion that this term finds support in the present specification. According to the invention, male sterility is used to produce a transgenic plant or to a part of a transgenic plant (page 3, lines 33-35), with the purpose of producing novel recombinant proteins (see page 1, lines 8-13). As indicated in the specification, a "part" of a plant encompasses fruits (page 4, lines 5-6). Furthermore, maize is an example of transgenic plant according to the invention (page 4, line 38 and following).

Additional support for the term can be found at page 4, lines 38-39 to page 5, line 1, wherein it is specified that "*in the case of maize, cultivating the transgenic plants with a view to production can be ensured in accordance with a scheme of the seed production type*". On page 5, lines 30-31, the present

specification further indicates that male sterile transgenic plants are "*normally used by seed companies to facilitate their production of seeds.*"

The specification also describes a method for seed or fruit production comprising pollinating male sterile plants with fertile counterparts and then harvesting the females (e.g., the fertilized male sterile plants that therefore produce seed or fruit, (see page 6, lines 12-18)).

Thus, applicants believe that the present application clearly contemplates and supports recitations directed to seed or fruit production. Thus, it is believed that the term "*plant cultivated for seed or fruit production*" is supported by the specification.

In the outstanding Official Action, claims 13-16 and 18 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

It is believed to be apparent that claims 19-22 have been drafted in a manner so as to obviate the contentions of the outstanding Official Action that the claimed invention is indefinite to one of ordinary skill in the art.

According to the Official Action, claim 13 was indefinite for reciting "rendered male sterile". It is believed that this objection is moot in view of the present amendment.

Claim 19 recites that the transgene of interest is introduced in a plant carrying cytoplasmic male sterility. The term "reduction" has been further corrected into the intended term "production", as inferred by the Official Action.

Applicants also believe that the objection of claim 16 is moot. Claim 16 has been canceled.

The Official Action also alleged that claim 18 was unclear. Applicants believe that new claim 22 meets all of the requirements of 35 USC §112. Claim 22 is drawn to a method for preventing transgene dissemination, wherein a plant is transformed with a plasmid vector containing a transgene of interest linked with AMS.

As a result, it is believed to be apparent that new claims 19-22 are definite to one of ordinary skill in the art.

Claim 13 was rejected under 35 USC §102(b) as allegedly being anticipated by SVAB et al. Claim 13 was then further rejected under 35 USC §102(e) as allegedly being anticipated by MALIGA et al.

The Official Action contends that SVAB et al. or MALIGA et al. disclose the transformation of a male sterile tobacco plant with a transgene. This rejection is traversed.

Applicants respectfully submit that the tobacco plant disclosed in SVAB et al. and MALIGA et al. fails to carry cytoplasmic male sterility (new claim 19), nor does the plant exhibit an AMS gene. Actually the tobacco disclosed in these

documents is functionally male sterile due to shortened filaments. However the tobacco plants are capable of producing viable pollen via hand pollination to obtain seeds (see SVAB et al., page 8526, right column, "plant lines" section, and MALIGA et al., column 12, line 67 to column 13, line 2).

On the contrary, male sterility according to the invention is an artificial genetic male sterility that renders the transgenic plant unable to produce viable pollen (see present specification, page 4, lines 27 to 34).

Thus, it is believed that SVAB et al. in view of MALIGA et al. fail to render obvious the claimed invention.

Claims 13-16 and 18 were rejected under 35 USC §102(b) as allegedly being anticipated by JORGENSEN. This rejection is respectfully traversed. On the contrary, applicants believe that the claimed invention is new and non-obvious in view of JORGENSEN.

As noted above, claim 19 is drawn to a method for preventing transgene dissemination wherein the transgene is introduced in a plant that carries cytoplasmic male sterility. Moreover, said transgenic plant is cultivated for seed or fruit production.

As recalled in the present specification, artificial genetic sterility may be conferred by cytoplasmic or nuclear male sterility (see page 2, lines 21-35). Nuclear male sterility genes may be recessive or dominant, whereas cytoplasmic male

sterility (CMS) is always a dominant characteristic. This discrepancy impacts how male sterility can be applied.

According to JORGENSEN, a plant with cytoplasmic male sterility cannot be used for the purpose of seed or fruit production.

We refer in particular to column 2, lines 4-18, where JORGENSEN states that "*for crops in which the product depends on fertilization the use of CMS is workable only if a restorer gene is available for the particular plant to permit restoration of fertility of the F1 hybrid*". This assertion means that a plant carrying cytoplasmic male sterility cannot be used to produce seed or fruit, but it requires crossing with a plant carrying a gene restoring fertility to produce a F1 hybrid which then can be used to produce seeds or fruits.

JORGENSEN further states that "*the method can also be used, however, for dominant sterile alleles in crops where seed is not an important product, e.g., spinach, cabbage, lettuce, broccoli, cauliflower and brussel sprouts*" (column 8, lines 21-24).

Thus, applicants believe that JORGENSEN actually describes a method for producing transgenic plants with a marker closely linked to a nuclear male sterile locus.

As to new claim 22, new claim 22 is drawn to a method for preventing transgene dissemination, wherein a plant is transformed with a plasmid vector containing a transgene of

interest genetically linked with an artificial male sterility gene.

However, JORGENSEN describes a method for producing transgenic plants with a marker closely linked to a nuclear male sterile locus. According to JORGENSEN, the marker and the nuclear male sterility gene are not introduced within the same plasmid vector. This stands further in contrast to the claimed method.

Thus, the method described by JORGENSEN comprises transforming a plant with a marker and then selecting the transformants that carry said marker at a single locus (see column 5, lines 21-36). Where the single locus is a male sterility locus, either the marker gene is introduced in a male sterile plant or a male sterile gene is introduced in a plant already transformed with the marker gene (see column 5, lines 60-68), and column 15, lines 29-37). Therefore, JORGENSEN does not disclose transforming a plant at the same time with a transgene of interest or an AMS gene linked therewith.

In the outstanding Official Action, claims 13-16 were rejected under 35 USC §102(b) as allegedly being anticipated by MARIANI et al. This rejection is also respectfully traversed.

MARIANI et al. describe a fertility restorer plant and method, wherein a plant with male sterility is crossed with the restorer plant. Applicants believe the method is limited to the crossing of plants with nuclear male sterility (see column 14,

lines 7-30). Applicants submit that the progeny resulting from this cross cannot prevent pollination. This is due to the fact that the fertility restorer gene confers male fertility to the progeny (see column 1, lines 8-14).

Thus, MARIANI et al. fail to disclose or suggest the claimed invention.

Claims 13-16 were rejected under 35 USC §102(e) as allegedly being unpatentable over FABIJANSKI et al. This rejection is respectfully traversed.

In imposing the rejection, the Official Action cites column 25, lines 20-39 and column 32, lines 23-62 of FABIJANSKI et al. The Official Action contends that a method of producing male sterile plants and sequential transformation of those plants with another transgene, or crossing of those male-sterile plants with another plant that has been transformed with a transgene is disclosed.

However, the FABIJANSKI et al. publication is drawn to a recombinant DNA molecule for the preparation of a male sterile plant along with the use of the plant to produce hybrid seeds. According to a particular embodiment, two DNA molecules can be used to produce the male sterile plant (see column 17, lines 19-24). Accordingly, the paragraphs cited by the Official Action do not refer to a transgenic plant carrying an artificial male sterility gene in conjunction with a transgene of interest at the same time. The disclosure relates to a plant carrying two genes,

non-genetically linked, conferring male sterility. This interpretation is further supported by FABIJANSKI et al., column 25, lines 40-43, that teach that *"where two recombinant DNA molecules are necessary to interfere with the function and/or development of a cell plant that is essential to pollen formation and/or function"*. The Examiner's attention is also directed to column 32, lines 23-26, which provides, *"more than one recombinant DNA molecule of the invention is used to produce male sterile plant"*.

Thus, applicants respectfully submit that FABIJANSKI et al. fail to disclose or suggest the claimed invention.

In the outstanding Official Action, it is also noted that the rejection of FABIJANSKI et al. in view of each of ELLSTRAND et al. and NYERS et al. was maintained. This rejection is respectfully traversed.

As noted above, the FABIJANSKI et al. publication is drawn to a recombinant DNA molecule for preparation of a male sterile plant and the use of the plant to produce hybrid seeds. However, it is respectfully submitted that FABIJANSKI et al. actually relate to a plant carrying two genes non-genetically linked, conferring male sterility. As noted above, we believe this interpretation is supported by FABIJANSKI et al. at column 25, lines 40-53; and column 32, lines 23-26. Thus, applicants respectfully submit that it cannot be stated that FABIJANSKI et al. would inherently disclose the prevention of transgene escape.


Moreover, as noted in our last response, FABIJANSKI et al., ELLSTRAND et al. and NYERS et al. all fail to actually use male sterility to prevent transgene dissemination. At best, the cited publications allude to the fact that male sterility may be a vehicle for preventing transgene dissemination. However, the steps for accomplishing transgene dissemination via male sterility are not found in those publications. As a result, one of ordinary skill in the art would lack the motivation and/or reasonable expectation of success that the use of male sterility would ensure an efficient prevention of transgene escape. Thus, applicants believe that the proposed combination of FABIJANSKI et al. in view of each of ELLSTRAND et al. and NYERS et al. fails to disclose or suggest the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that the present application is now in condition for allowance, with claims 19-24, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

Respectfully submitted,

YOUNG & THOMPSON

By



Philip A. DuBois
Agent for Applicants
Registration No. 50,596
745 South 23rd Street
Arlington, VA 22202
Telephone: 521-2297

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